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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,646	11/16/2005	David G. Quinn	5935/117	1392

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BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT PAPER NUMBER

3763

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/529,646

Applicant(s)

QUINN, DAVID G.

Examiner

Christopher D. Koharski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19 and 22-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 6-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19 and 22-31 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/3/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 1-4 and 6-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group (Group II elected), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/14/2006.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 4/03/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Claim Objections

Claim 18 objected to because of the following informalities: Regarding dependant claim 18, "...said port..." is referenced with a lack of antecedent basis. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17-19, 22-25 and 30-31 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 22 of U.S. Patent No. 7,048,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the current pending application are anticipated by the claims in the cited US patent.

Application claim 17 requires:

17. A catheter for delivering fluid into, or aspirating fluid out of, a body cavity or cavities, comprising:

a) a multiple lumen tube containing at least first and second lumens and having a proximal end and a distal end, said tube containing a septum separating said first and second lumens, said tube being formed so that said first lumen is shorter than said second lumen at said distal end whereby said second lumen opens and said septum terminates at a predetermined distance from where said first lumen opens at said distal end of said multiple lumen tube;

b) a first bolus having a nose end and a connector end, said first bolus having an axial passage therethrough;

c) said distal end of said multiple lumen tube being seated in said axial passage at said connector end of said bolus;

d) a single lumen catheter tube seated in said axial passage of said first bolus at its nose end, said single lumen tube extending from a proximal end to a distal end and a port in said distal end.

While patent claim 1 requires:

A nasogastric/jejunal catheter comprising:

a) an elongated, flexible first catheter tube containing first and second lumens extending from a proximal end of the first tube to a distal end thereof;

b) a first bolus having a connector end connected to said distal end of said first catheter tube, said first bolus having a nose end and containing a first passage and a second passage therein communicating with said first and second lumens, respectively, of said first catheter tube at said connector end of said first bolus;

c) said first passage extending axially through said first bolus to an opening in said nose end of said first bolus, said second passage extending axially through said first bolus to a port opening radially through a side of said first bolus;

d) an elongated second catheter tube containing a lumen extending from a proximal end of the second tube to a distal end thereof, said proximal end of said elongated second catheter tube being connected to said nose end of said first bolus so that said second catheter tube lumen is in communication with said first passage in said first bolus;

e) a second bolus connected to said distal end of said second catheter tube, said second bolus having a nose end and a connector end and containing a passage therein communicating with said lumen in said second catheter tube at said connector end of said second bolus;

f) said second bolus having a port therein communicating with said passage in said second bolus.

Thus it is apparent that the application claims are broader than the patent claims and the subsequent patented independent and dependant claims 1-22 encompass application claims 17-19, 22-25 and 30-31. Following the rationale in *In Re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting a terminal disclaimer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-19, 22-25 and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Cruz et al. (5,571,093). Cruz et al. discloses a multiple-lumen catheter.

Regarding claims 17-19, 22-25 and 30-31, Cruz et al. discloses a catheter that comprises a multiple lumen catheter (223,224) with first and second lumens with the

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first lumen being shorter than the second with a first bolus (264) having an axial passage there thorough with an nose end and connection end, with a single lumen running there through (247) with a second bolus on the distal end of the second catheter tube (221), wherein the bolus is bullet shaped (Figure 12-13) (col 5, ln 35-68). The catheter tube is formed of a resilient plastic (col 3, ln 19-22) that contains a septum between the two lumens (Figure 14). Cruz et al. also discloses fluid ports are present in the bolus member at the termination of the catheter lumens (249,250).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26-29 are rejected under 35 U.S.C 103(a) as being unpatentable over Cruz et al. in view of Martin et al. (5,195,962). Cruz et al. meets the claim limitations as described above except for a cylindrical shaped plug.

However, Martin et al. teaches a triple lumen catheter.

Regarding claims 26-29, Martin et al. teaches the use of end plugs (56,60) in a multiple lumen catheter with a bolus tip (Figures 2-5).

At the time of the invention, it would have been obvious to include the end plugs of Martin et al. to the system of Cruz et al. in order to direct the lumen flow or to close the lumen off to port flow through the catheter elongate body. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Martin et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

10/9/06

CPK
Christopher D. Koharski
AU 3763

[Signature]
[Faint, illegible text]